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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/717,817

11/20/2003

Xi Chu

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EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

05/01/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/717,817	<b>Applicant(s)</b> CHU, XI	
	<b>Examiner</b> CHERYL MILLER	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) 1-28,40-45,47-49,52-63 and 84-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-39, 46, 50-51, 64-83, and 87-88 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/15/2007</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments with respect to claims 29-40, 50, and 51 have been considered but are moot in view of the new ground(s) of rejection.

### ***Election/Restrictions***

Applicant's election of sub species 1 (triangular shaped hinge) and sub sub sub species 2 (graphite) is acknowledged. Claims 40, 52-63, and 84-86 are further withdrawn from the examiner as being directed to a non-elected invention. The triangular hinge opening embodiment was only found by the examiner to be a full through-hole (not only a portion or half of the opening being a through hole).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 29-34 and 38-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Lapeyre et al. (US 6,395,024 B1). Lapeyre discloses a prosthetic valve (fig.2 for example) comprising an annular valve body (105) having three pairs of symmetrically placed hinges (hinge/pivot regions 125+210) extended from the annular body and three leaflets (110) mounted in the annular valve body (105) and configured to translate between and open (fig.2) and closed

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(fig.3) position, each leaflet (110) having opposed ears (205) and a flat edge (1415; fig.15) adjacent each ear, each ear (205) pivotably received in hinge openings (125+210; received in recess 210), each hinge opening (210) including a hole (125) extending entirely through the valve body. Lapeyre discloses each leaflet (110) to comprise a central surface with a curved outer edge (1410) for engaging the annular body and an obliquely angled inner edge (seen at top of fig.14 and 19a-19c) for engaging adjacent leaflets and two flat segments (1415) adjacent to each ear (205). Lapeyre discloses the hinges to have stop means (130, 200 or 300). Lapeyre discloses the hinges to have three supports (215, 200 or walls of 125) for guiding the leaflets. Lapeyre discloses the valve body and leaflets to be formed of pyrolytic carbon (col.7, lines 32-47). Lapeyre shows the hinges to be triangular shaped openings with flat bottoms (see 125, fig.3 for example).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29-34 and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knoch et al. (US 4,923,465) in view of Lapeyre et al. (US 6,395,024 B1). Referring to claims 29-33 and 38-39, Knoch discloses a prosthetic valve (fig.1, 6, for example) comprising an annular valve body (10) having hinges (17) extended from the annular body with through holes (see figs) and a leaflets (12) mounted in the annular valve body (10) and configured to translate between an open and closed position, the leaflet (10) having opposed ears (16), each ear (16)

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pivotally received in hinge openings (17), each hinge opening (17) including a hole extending entirely through the valve body (col.2, lines 5-10). Knoch discloses the prosthetic valve substantially as claimed, however does not show a tri leaflet configuration (Knoch discloses monocuspid or bicuspid valve leaflets, but not tricuspid). Lapeyre teaches in the same field of prosthetic valves, the use of three leaflets instead of one or two (see fig.6), wherein when three leaflets are used, they each have a curved outer edge that contacts the valve body and flat opposite edges that contact adjacent leaflets. As natural valves are bicuspid or tricuspid (see Knoch, col.1, lines 7-12), it would seem obvious to use three leaflets to mimic that movement in natural tricuspid valves in the body. Lapeyre shows such a tri leaflet configuration. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Knoch's prosthetic valve with leaflet and cooperating open hinge structure having one or two leaflets, with Lapeyre's teaching of using three leaflets on prosthetic valves, in order to provide a leaflet structure that more closely mimics the movement of natural three leaflet valves. It makes common sense to use Knoch's leaflet hinge structure with three leaflets instead of one or two, as three leaflets prosthetic valves are well known in the art and they mimic the shape of the natural three leaflet valve.

Referring to claim 34, Knoch is silent to mention any materials for the annular body and leaflets. Lapeyre teaches in the same field of prosthetic valves, the use of pyrolytic carbon on both the annular body and leaflets as such a material is a rigid material biocompatible in the body (col.7, lines 31-47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Knoch's prosthetic valve with Lapeyre's teaching of choice

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of material for prosthetic valves (pyrolytic carbon) in order to provide a valve that is durable and biocompatible in the body.

Claims 35-36, 46, 50-51, 64-72, 74-82, and 87-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knoch et al. (US 4,923,465) in view of Lapeyre et al. (US 6,395,024 B1) as applied to claim 29 above, and further in view of Molina (US 2003/0114925 A1). Knoch in view of Lapeyre discloses a prosthetic valve substantially as claimed. Knoch in view of Lapeyre discloses an annular body with three leaflets, the valve body and leaflets made of pyrolytic carbon (see above). Knoch in view of Lapeyre does not disclose however, any specific to the type of pyrolytic carbon (whether it is a composite or not or aligned layers). Molina teaches in the same field of prosthetic valves, the use of a material being a composite of carbon (graphite) fibers and pyrolytic carbon as an improvement to conventional pyrolytic carbon (P0002, P0004, P0012). Such a layered composite is engineered carbon and has improved structural properties due to the reinforcing fibers (P0011). Molina discloses use of carbon fibers that may be chopped short or continuous, however is silent to mention the diameter of the fibers (unclear if nanofibers). Carbon (graphite) fibers are known to be nanosized, thus it would seem inherent that Molina's carbon fibers are nanofibers, however if not inherent, it would have been obvious for the carbon fibers to have nano diameters, since Molina discloses variation of processing parameters and mathematical size equations that would encompass a endless variety of diameters (P0024, P0025, P0028-P0030), since wherein the general conditions of a claim are disclosed in the prior art (carbon fibers having a mathematical formula for a variety of sizes) it is not inventive to discover the optimum or workable ranges (nano sized fibers) by routine

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experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Knoch in view of Lapeyre's prosthetic valve body and leaflets with Molina's teaching of a specific composite material for prosthetic valves, in order to provide a valve body and leaflets with improved strength. Layered planes of the material is an inherent property of the pyrolytic carbon.

Claims 73 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knoch et al. (US 4,923,465) in view of Lapeyre et al. (US 6,395,024 B1) and Molina (US 2003/0114925 A1) and further in view of Meunier et al. (US 6,261,421 B1). Knoch in view of Lapeyre and Molina discloses the substrate to comprise graphite and radiopaque material (P0026, tantalum, tungsten; 0-20%), however is silent to mention a binder. Meunier teaches in the same field of heart valves, the use of binders with carbon/graphite coatings and carbon/graphite substrates as common use in the manufacturing process of such materials (col.4, lines 35-54). Meunier does not disclose a specific amount, however it would have been obvious to have between about 5-20 % binders since wherein the general conditions of a claim are disclosed in the prior art (presence of binders in carbon/graphite materials) it is not inventive to discover the optimum or workable range by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

In the alternative to the above rejection, claims 51, 66, 67, 76, 77, 87, and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knoch et al. (US 4,923,465) in view of Lapeyre et al. (US 6,395,024 B1) and Molina (US 2003/0114925 A1) and in further view of

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Woo et al. (US 6,761,736 B1). Knoch in view of Lapeyre and Molina disclose a prosthetic valve made of a pyrolytic carbon outer coating (see above). If not inherent that the outer pyrolytic carbon coating contains parallel oriented planes, it would have been obvious. Woo teaches in the same field of prosthetic valves, the use of alternate outer coatings, graphite may be used as an alternative to pyrolytic carbon, both compatible materials for use with heart valves (col.3, line 62-col.4 line 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Knoch in view of Lapeyre and Molina's prosthetic valve having an outer layer of pyrolytic carbon, with Woo's teaching of use of graphite as an alternate coating material to pyrolytic carbon, in order to provide a prosthesis with a biocompatible outer surface with oriented parallel planes (inherent to graphite).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,



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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/  
Examiner, Art Unit 3738

/Corrine M McDermott/  
Supervisory Patent Examiner, Art Unit 3738

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